REMARKS

Reconsideration is requested.

Claims 64, 67, 68, 70 and 73 have bee additionally canceled, without prejudice.

Claims 53, 57-73, 81-90, 92, 96, 98, 99 and 101-104 are pending. Claims 53, 57-63, 65, 66, 69, 71, 81-90, 92, 96, 98, 99 and 101-104 will be pending upon entry of the present Amendment. Support for the claim revisions may be found throughout the specification.

The Section 112, second paragraph, rejection of claims 53, 57-73, 81-90, 92, 96, 98, 99 and 101-104 is obviated by the above. Withdrawal of the Section 112, second paragraph, rejection is requested.

The Section 103 rejection of claims 53, 57-73, 81-90, 92, 96, 98, 99 and 101-104 over Tamime (1985, Yoghurt; Science and Technology, Pergamon Press, New York, pages 18, 25-26, 60, 103-104, 111, 145-146, 235-238, 241-243, 255-256 (referred to as R1 by the Examiner and hereinafter)), Reddy (WO 98/18349 (referred to as R2 by the Examiner and hereinafter)) and Takahashi (EP 1 206 909 (referred to as R3 by the Examiner and hereinafter)), is traversed. Reconsideration and withdrawal of the rejection are requested

The Examiner is understood to believe that it would have been obvious to one of ordinary skill in the art to have made the claimed invention by allegedly applying the stabilizers from either R2 or R3 to the process of R1. The Examiner is requested to advise the applicants in a further Action in the event the basis for the rejection has been misunderstood.

Reconsideration and withdrawal of the rejection are requested in view of the above, the remarks of record and the following comments.

R1 discloses a process for the production of fermented milk including yoghurt, yoghurt beverage, stirred yoghurt and the like. The process outlined on page 236 discloses the addition of sugar and/or stabilizers to milk, followed by homogenization, heat treatment and inoculation with a starter culture. There is no disclosure or suggestion of which specific stabilizer(s) are suitable for the process.

The following Table 2.9 from page 26 of R1 lists a variety of different stabilizers **which are permitted** by FAO/WTO and the Food & Drugs Act for use in the manufacture of diary products, including yoghurt.

TABLE 2.9. *Classification and functions of gums which could be used during the manufacture of yoghurt*

Natural gums	Modified gums	Synthetic gums
Plant	Cellulose derivatives (1)	Polymers*
Exudates	Carboxymethylcellulose	Polyvinyl derivatives
Arabic (1, 3)	Methylcellulose	Polyethylene derivative
Tragacanth (1)	Hydroxyethylcellulose	
Karaya	Hydroxypropylcellulose	
Extracts	Hydroxypropylmethylcellulose	
Pectins (2, 3)	Microcrystallinecellulose	
Seed Flour		
Locust (Carob) (1)	Microbial fermentation	
Guar (1)		
	Dextran	
	Xanthan (1, β)	
Seaweed		
Extracts	Miscellaneous derivatives	
Agar (2, 3)		
Alginates (1, 2, 3)	Low-methoxy pectin	
Carrageenan (2, 3)	Propylene glycole alginate	
Furcellaran (1, 2, 3)	Pre-gelatinised starches	
	Modified starches	
Cereal starches (1, 2, 3)	Carboxymethyl starch	
Wheat	Hydroxyethyl starch	
Corn	Hydroxypropyl starch	
Animal		
Gelatin		
Casein		
Vegetable		
Soy protein		

* Limited in its application in yoghurt, since it is not listed in the Food and Drugs Act (1975, 1980) or FAO/WHO (1976).
The permitted level of these stabilising compounds in yoghurt is 5000 mg/kg with the exception of pectins, gelatin and starches, i.e. 10 g/kg.
Figures in parentheses indicate the function of the hydrocolloid, i.e. (1) thickener, (2) gelling agent and (3) stabiliser.

After: Powell (1969), Glicksman (1969; 1979), Pedersen (1979).

Table 2.9 describes low methoxy pectin as the only specific example of a pectin permitted for use as a stabilizer. R1 does not disclose the actual use of a pectin as a stabilizer. Nor does R1 disclose the use of a high ester pectin, let alone a high ester depolymerised pectin as presently claimed.

Furthermore, the following page 27 of R1 highlights that stabilizers are often added as a blend.

R1

(b) pumping of the coagulum to a plate/tubular cooler;
(c) mixing to incorporate the fruit/flavours into the coagulum, followed by pumping to the filling/packaging machine;
(d) subsequent post-fermentation heat treatment of the coagulum for the manufacture of "Pasteurised, UHT or Long-life Yoghurt", and, as a result, the yoghurt may become less viscous or, in extreme cases, may show whey separation; the addition of stabilisers can overcome these defects.

Stabilisers are sometimes referred to as hydrocolloids, and their mode of action in yoghurt includes two basic functions: firstly, the binding of water, and secondly, promotion of an increase in viscosity (Boyle, 1972). Thus, the molecules of stabiliser are capable of forming a network of linkages between the milk constituent(s) and themselves due to the presence of a negatively charged group, e.g. hydrogen or carboxyle radicals, or to the presence of a salt possessing the power to sequester calcium ions. These negative groups are concentrated at the interfacial areas, and according to Boyle (*loc. cit.*), Ingenpass (1980) and Dexter (1976) the binding of water into the basic mix is achieved by the stabiliser as follows:

(a) it binds the water as water of hydration;
(b) it reacts with the milk constituents (mainly the proteins) to increase their level of water hydration;
(c) stabilises the protein molecule to form a network that retards the free movement of water (see Figs. 2.8 and 2.9).

Therefore, the functions of hydrocolloids in yoghurt are as:

(a) gelling or thickening agents; and
(b) stabilising agents.

As can be seen from Table 2.9, there is a wide range of compounds which can be added to milk for the production of a viscous yoghurt, and these stabilisers can be added as single compounds or as a blend. The latter approach is more widely used, since most commercial preparations are a mixture of stabilising compounds (unless it is declared otherwise).

The object of blending these compounds together is to achieve a specific function or, in the majority of cases, to overcome one of the limiting properties associated with a specific compound. For example, a single stabilising compound (X) may be suitable for the manufacture of a fruit/flavoured yoghurt, but it may not be suitable, on its own, for the production of frozen, dried or pasteurised yoghurt, and hence the choice of a particular type of "stabiliser" is dependent on a multitude of factors, including:

1. Functional properties, effect and/or mode of action of the selected compound.

2. Optimum concentration to be used.

The level of stabiliser(s) in yoghurt is sometimes governed by legislation (FAO/WHO, 1976; UK Food Standards, 1975) and/or side effects, i.e. appearance or undesirable mouth-feel, which could

Specifically, R1 teaches the following in this regard:

> "The object of blending these compounds together is to achieve a specific function or, in the majority of cases, to overcome one of the limiting properties associated with a specific compound. For example, a single stabilizing compound (X) may be suitable for the manufacture of a fruit/flavoured yoghurt, but it may not be suitable, on its own, for the production of frozen, dried or pasteurised yoghurt, and hence the choice of a particular type of "stabilizer" is dependent on a multitude of factors"

As such, it is clear that Table 2.9 does not indicate the general suitability of the stabilizers mentioned therein.

The factors determining suitability are further discussed on the following pages 30-31 of R1:

be caused by the addition of too large a quantity. Some recommended levels of stabiliser for the manufacture of yoghurt are:

(i) 0.02–0.2 % of pectins or some modified starches (Winterton and Meiklejohn, 1978; Zmarlicki, Pijanowski and Molska, 1977);
(ii) 0.2–0.5 % of agar-agar, locust (carob) gum, guar gum, alginate, gelatin or carrageenan (Volker, 1972; Schrieber, 1973; Ledder and Thomasow, 1975; Steinitz, 1975);
(iii) 1–2 % of some starch preparations (Thomasow and Hoffmann, 1978).

Another factor which determines the level of stabiliser added to the yoghurt milk is the percentage of milk solids present, and according to Hall (1975) the optimum concentrations for a gelatin/plant gum mixture were 0.5, 0.45, 0.4, 0.3 and 0.25 % to yoghurt milks containing 12.5, 14.5, 16.5, 19.0 and 22.0 % milk solids respectively.

3. Toxic or inhibitory effects

Although tragacanth and locust (carob) gum are still awaiting toxicological clearance for use in foodstuffs (FAO/WHO, 1976), in general, stabilising compounds do not, at the rates normally employed, inhibit the yoghurt organisms.

4. Legal aspect

The statutory regulations differ with the country concerned, and not all stabilising compounds are permitted for the production of yoghurt.

5. Solubility and dissolution

Some starch preparations and Na-carrageenan are soluble at a low temperature, and hence they can be added to cold milk during the preparation of the basic mix. The majority of the stabilising compounds are, however, only soluble at higher temperatures, e.g. 50–85°C (with the exception of agar-agar at 90–95°C), so that in practice these stabilisers are added to warm milk before pasteurisation, or alternatively to hot milk after the heat treatment. In some instances complete dissolution of a particular stabiliser blend, e.g. one which contains some starch preparation, may necessitate a holding time at high temperature in order for the mixture to become active as a "stabiliser".

In view of the different properties of these compounds, it is difficult to recommend one method for incorporation into the basic mix, but the following points may help to overcome any problems:

(i) follow the instructions provided by the manufacturer; or in the absence of any information
(ii) mix the stabiliser with the milk powder and add to the water or milk with high-speed stirrer at the temperature recommended for the milk powder;
(iii) alternatively, mix the stabiliser with the sugar and add to the basic mix under high-speed agitation at the temperature recommended for the sugar;
(iv) hydrate the stabiliser (e.g. gelatin powder) in water or milk, and then add to the basic mix with high-speed stirring.

6. *Effect on the casein*

The addition of some hydrocolloids (Na-carboxymethyl-cellulose, guar gum and locust gum) at levels as low as 0.05 % to sweet milk can destabilise the casein micelle (Powell, *loc. cit.*), and although the destabilised casein micelles will eventually coagulate, the matrix has a rather limited ability to retain water, and as a result syneresis becomes evident. Furthermore, such destabilised casein can give rise to a course coagulum with an open texture. The problem can be minimised, however, by blending the above compounds with carrageenan or aliginates (see also Dexter, *loc. cit.*).

7. *Processing conditions*

As can be seen from Chapter 5, various yoghurt-based products have been developed, and the quality of these is dependent on the addition of stabilisers. For example:

(i) "Pasteurised, UHT or Long-life" yoghurt—it is recommended that a gelling agent is added consisting of a blend of locust gum and agar-agar and/or xanthan (Anon., 1980a); the presence of starch derivatives (diamylopectin glycerol ether or diamylopectin phosphate) can improve the appearance of heat-treated yoghurt (Vanderpoorten and Martens, 1976).

(ii) "Frozen" yoghurt—an unspecified mixture of stabilisers/emulsifiers is recommended by Gautneb, Steinsholt and Abrahamsen (1979), but the addition of modified starch proved unsatisfactory (Winterston and Meiklejohn, *loc. cit.*).

(iii) "Stirred" yoghurt—a blend of 1 % Na-proteinate (possibly Na-caseinate), 0.1 % Frimulsion J5, 0.1 % Genu Gum CH 200, 0.3 % Genu carrageenan with Malto-Dextrin or 0.16 % Frimulsion JQ improved the viscosity of the product (Luczynska *et al.*, 1978).

(iv) "Drinking" yoghurt—an agar-agar based stabiliser is added at a rate of 0.25 %, and this helps to maintain the suspension of fruit in the product (Morley, 1978).

(v) 'Freeze-dried Dahi'—the quality of the product was improved by the addition of corn starch and lecithin or glycerol monostearate to the fermented milk prior to drying (Baisya and Bose, 1975).

Since casein precipitation may occur in "sweet milk" or during the development of acid, some of the stabilisers may be added to the yoghurt after the formation of the coagulum. In this case it is recommended that the stabilising compound (e.g. liquified agar-agar and/or "pre-swollen" gelatin) is mixed with the sugar and then incorporated into the coagulum.

8. *Solidification characteristics*

The majority of stabilisers used in the production of yoghurt will solidify at ordinary refrigeration temperature, with the exception of gelatin and agar-agar which solidify at 25°C and 42–45°C respectively. These latter stabilising compounds can, therefore, cause problems during the cooling stage, i.e. difficulty in pumping and/or packaging, and in addition the use of gelatin may give the coagulum a "rough texture". This latter fault can be reduced or eliminated by passing the coagulum through a fine mesh screen/sieve.

Specifically, Section 6 of page 31 of R1 states as follows:

> “The addition of some hydrocolloids … [i.e. stabilizers, see p.27, second paragraph] at levels as low as 0.05% to sweet milk can destabilise the casein micelle …, and although the destabilized casein micelle will eventually coagulate, the matrix has a rather limited ability to retain water, and as a result syneresis become evident”.

Section 7 on page 31 of R1 further states the following:

> “Since casein precipitation may occur in “sweet milk” or during the development of acid, some of the stabilizers may be added to the yoghurt after the formation of the coagulum. In this case it is recommended that the stabilizing compound … is mixed with the sugar and then incorporated into the coagulum”.

As such, the whole of R1 recognizes the technical problem which the present invention seeks to overcome i.e. that some “stabilizers” can destabilize neutral milk and therefore have to added after fermentation.

In view of the above, it is clear that R1 provides no reason for the ordinarily skilled person to have diverted from the accepted wisdom in the art that pectin is not a suitable stabilizer for addition to neutral milk prior to fermentation.

Reddy (R2) describes the fortification of food stuffs with calcium. In particular, R2 describes a hydrolysed pectin-calcium complex that can be used to fortify milk beverages without protein destabilization or imparting an undesirably high viscosity. At page 2, lines 21 to 22, R2 discloses that the hydrolysed pectin is demethoxylated to more than 50%, preferably more than 75% (i.e. a low ester hydrolyzed pectin). R2 discloses only the production of UHT milk and not fermented milk products.

R2 discloses low ester hydrolyzed pectins only, whereas the presently claimed invention requires the presence of a high ester depolymerized pectin. Therefore, even if the ordinarily skilled person were to use a stabilizer from R2 in the process of R1, which would not have been obvious, they would not have arrived at a process of the presently claimed invention.

Furthermore, the applicant submits that in attempting to combine the teachings of R1 and R2 the Examiner is using impermissible hindsight. R2 discloses only the production of fortified stable milk. R2 provides no teaching or suggestion that this product is suitable for fermentation in order to produce stabilized diary products. Despite this, the Examiner speculates in section 16 of the Office Action that

> "the stable [sic, stabilized?] milk product will remain stable even after gradual acidification caused by fermentation".

R2 does not provide any basis for such a conclusion however. The conclusion is made with an impermissible use of hindsight and the Section 103 rejection should be withdrawn.

The ordinarily skilled person would not have had any reasonable expectation from the cited art alone that the milk of R2 could be fermented to yield stable diary products. The combined teachings of R1 and R2 would not have made the claimed invention obvious. The additional teachings of R3 fail to cure the deficiencies of R1 and/or R2.

Takahashi (R3) discloses the stabilization of non-fermented, directly acidified milk beverages with a high ester low-molecularized pectin.

The Examiner appears to believe that R1 and R3 in combination teach all the aspects of the claimed invention. However, according to MPEP § 2143.01 IV ("MERE STATEMENT< THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH PRIMA FACIE OBVIOUSNESS"), in the absence of some objective reason to combine the teachings, it is not sufficient to establish a *prima facie* case of obviousness by merely identify corresponding aspects in the prior art.

The Examiner has failed to provide any justification as to why, prior to the priority date, the ordinarily skilled person would have combined references R1 and R3 to allegedly make the presently claimed invention. R3 clearly addresses a different technical problem to R1. Namely, R3 seeks to provide a stable, directly acidified milk beverage with low viscosity, whereas page 236 of R1 is concerned with traditional processes for the provision of fermented yoghurt. Therefore, the ordinarily skilled person would not have sought to combine aspects of these two disclosures to allegedly make the presently claimed invention.

Furthermore, the ordinarily skilled person would not have applied the stabilizer of R3 to the process of R1 with any reasonable expectation of success.

It is commonly known in the art that greater than 0.2% high ester, high molecular weight pectin added to neutral milk induces phase separation (see page 2, line 11 and page 4, lines 11 and 12 of the description and the attached Maroziene *et al.* ("Interaction of pectin and casein micelles" Food Hydrocolloids 14 (2000) 391-394), and specifically § 4 (Conclusions) of same. This is also eluded to in R1 (see page 30, lines

3 and 4). Also, it was commonly known that high ester, high molecular weight pectin stabilizes milk at acidic pH (see sentence bridging pages 3 and 4 of the description and the attached Macfadyen *et al.*("New Uses of Pectin in the Dairy Industry" Int. Food Ing. 1992, vol ½, 11-14). Therefore, one of ordinary skill comparing R3 with the common knowledge of the art would have appreciated that the degree of polymerization does not change the stability of the acidified milk beverage but merely lowers its viscosity.

Equipped with this knowledge, the person ordinarily skilled in the art would not have had any reasonable expectation that the low-molecularized pectin of R3 would not cause the instability seen with normal pectins in neutral milk, let alone successfully stabilize the milk during fermentation to yield a stabilized diary product with enhanced viscosity and creaminess.

The claimed invention would not have been obvious over the combination of cited art. Withdrawal of the Section 103 rejection is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required.

Respectfully submitted,

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